



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

11 MAY 2016

MEMORANDUM FOR SGOM

ATTN: MAJ OANH TRAN

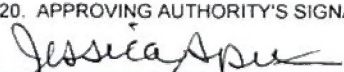
FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Exploring Best Practices in Advance Care Planning** presented at/published to **SAMHS and Universities Research Forum, UTSA Main Campus, San Antonio, TX 20 May 2016** with MDWI 41-108, and has been assigned local file #**16187**.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol) Oanh Tran, Maj, O-4, SGOM	3. GME/GHSE STUDENT: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	4. PROTOCOL NUMBER: N/A
5. PROTOCOL TITLE: (NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)			
6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED: Exploring Best Practices in Advance Care Planning			
7. FUNDING RECEIVED FOR THIS STUDY? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO FUNDING SOURCE:			
8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
9. IS THIS MATERIAL CLASSIFIED? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.? <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO NOTE: If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.			
11. MATERIAL IS FOR: <input checked="" type="checkbox"/> DOMESTIC RELEASE <input type="checkbox"/> FOREIGN RELEASE CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.			
<input type="checkbox"/> 11a. PUBLICATION/JOURNAL (List intended publication/journal.)			
<input type="checkbox"/> 11b. PUBLISHED ABSTRACT (List intended journal.)			
<input checked="" type="checkbox"/> 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.) SAMHS and Universities Research Forum, UTSA Main Campus, San Antonio, TX; May 20, 2016			
<input type="checkbox"/> 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meeting.)			
<input type="checkbox"/> 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)			
12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).			
DATE April 25, 2016			
13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Tran, Oanh N., oanh.tran.1@us.af.mil			14. DUTY PHONE/PAGER NUMBER 210-292-4904; 210-594-6779
15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.			
LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Oanh Tran	O-4/Maj	MDOS/MDOG/SGOM	59 MDW
b.			
c.			
d.			
e.			
f.			
I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401 JP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.			
16. AUTHOR'S PRINTED NAME, RANK, GRADE		17. AUTHOR'S SIGNATURE TRAN.OANH.N.1289779570	18. DATE April 25, 2016
19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE JESSICA R. SPITLER, Lt Col, USAF, BSC Commander, 59 MDOS		20. APPROVING AUTHORITY'S SIGNATURE 	21. DATE 29 April 16

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS			
1st ENDORSEMENT (59 MDW/SGVU Use Only)			
TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED <div style="text-align: center; font-weight: bold;">4/28/2016</div>	23. ASSIGNED PROCESSING REQUEST FILE NUMBER <div style="text-align: center; font-weight: bold;">16187</div>	
24. DATE REVIEWED <div style="text-align: center; font-weight: bold;">9 May 2016</div>		25. DATE FORWARDED TO 502 ISG/JAC	
26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: <input type="checkbox"/> NO <input type="checkbox"/> YES If yes, give date. _____ <input type="checkbox"/> N/A			
27. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED <div style="padding-left: 20px;"> -Member submitted 3039 on 4/28/16, but had submitted the wrong 3039. Was sent back for update. Received updated form on 5/4/2016. The abstract is approved. </div>			
28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER <div style="text-align: center; font-weight: bold;">Rocky Calcote, PhD, Clinical Res. Administrator</div>		29. REVIEWER SIGNATURE CALCOTE.ROCKY.D.11782 45844 <small>Digitally signed by CALCOTE.ROCKY.D.1178245844 DN: c=US, o=U.S. Government, ou=DoD, ou=PR, ou=USAF, cn=ROCKY.D.1178245844 Date: 2016.05.09 06:25:40 -0500</small>	
30. DATE		31. DATE RECEIVED	
32. DATE FORWARDED TO 59 MDW/PA			
33. COMMENTS <input type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		35. REVIEWER SIGNATURE	
36. DATE		37. DATE RECEIVED <div style="text-align: center; font-weight: bold;">11 May 2016</div>	
38. DATE FORWARDED TO 59 MDW/SGVU <div style="text-align: center; font-weight: bold;">11 May 2016</div>			
39. COMMENTS <input checked="" type="checkbox"/> APPROVED (In compliance with security and policy review directives.) <input type="checkbox"/> DISAPPROVED			
40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER <div style="text-align: center; font-weight: bold;">Christopher Carwile, TSgt/E-6, NCOIC, PA</div>		41. REVIEWER SIGNATURE CARWILE.CHRISTOPHER, STEWART.1280477229 <small>Digitally signed by CARWILE.CHRISTOPHER, STEWART.1280477229 DN: c=US, o=U.S. Government, ou=DoD, ou=PR, ou=USAF, cn=CARWILE.CHRISTOPHER, STEWART.1280477229 Date: 2016.05.11 11:06:52 -0500</small>	
42. DATE <div style="text-align: center; font-weight: bold;">11 May 2016</div>		43. DATE RECEIVED	
44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> COULD NOT BE REACHED <input type="checkbox"/> LEFT MESSAGE			
45. COMMENTS <input type="checkbox"/> APPROVED <input type="checkbox"/> DISAPPROVED			
46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER		47. REVIEWER SIGNATURE	
48. DATE		49. DATE RECEIVED	

Exploring Best Practices in Advance Care Planning

Oanh Tran, MD, Danielle Kusserow Bersabe, MD, Jennifer Kyler, RN

Internal Medicine Department, Wilford Hall Ambulatory Surgical Center, San Antonio, TX, 78236

Background: The factors that influence completion of advance care planning for elderly adults in the primary care setting are poorly understood. System factors such as expansion of technological and medical options added to lists of tasks primary care providers are expected to complete in ever shrinking visit time, provider factors such as discomfort with end-of-life discussions, and patient factors such as impaired communication all contribute to low rates of completion. We hypothesized that prioritized utilization of motivational interviewing during a visit specified to address advance care planning will enhance completion rates of appropriate planning.

Methods: A single provider was given time in an outpatient face-to-face visit dedicated to an advance care planning discussion that included goals for medical care and individual values and beliefs as they related to the variety of options available. The patient was invited to conclude the visit with filing out the Directive to Physicians and Family or Surrogates forms and medical power of attorney documents to bear a legal presence of the decisions made. ICD-10 coded counseling and discussion regarding advance directives or end of life care planning and decision with patient and/or surrogate for the internal medicine clinic were compared for 2 months prior to intervention, and 2 months post-intervention.

Results: Completion rate and patient satisfaction increased significantly during the visit dedicated to end-of-life counseling. We discovered that barriers to successful assertion of patient autonomy in the end-of-life included lack of opportunity to discuss choices with the primary care provider, missing or inadequate documentation, and lack of accessibility of the end-of-life documents to providers at the point of care.

Conclusion: The model for ideal advance care planning to best support patient autonomy and decrease family distress when the health and decisional or communication capacity of an elderly patient declines is not known. We modeled a motivational interviewing and shared decision-making strategy within a multidisciplinary team with improved advance care planning completion amongst elderly adults in a primary care clinic.

No financial connections were established to support the production of this work.

The views expressed are those of the author and do not reflect the official views or policy of the Department of Defense or its Components.

Is My Project Research?

This checklist is designed to provide investigators at the 59th Medical Wing (59 MDW) a simplified means of deciding if their proposed project or activity may constitute research involving human subjects, thus requiring further review and approval by an Exempt Determination Official (EDO) or the 59 MDW Institutional Review Board (IRB).

This checklist is unofficial and **DOES NOT** allow an investigator to make their own determination as to whether their project or activity is or is not research involving human subjects. In accordance with DoDI 3216.02_AFI 40-402, Enclosure 2, §11.c., investigators are not authorized to make their own research determinations. The 59 MDW IRB, an EDO, or the Surgeon General's Research Oversight and Compliance Division (SGE-C) are the only authorized officials to determine if an activity is research involving human subjects [DoDI 3216.02_AFI 40-402, Enclosure 3, §3.a.(1).(a)].

1. Project Regulatory Category:

Does the activity involve any of the following?

<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	A drug or device used outside of usual medical practice, including non-FDA-approved agents, or off-label uses of FDA-approved drugs or devices being administered to one or more humans.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	The safety and/ or effectiveness of a drug (FDA approved or non-FDA approved) or regulated device will be evaluated or be compared to that of another.
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Data from the activity of an active group or a control group will be submitted to, or held for inspection by the FDA in support of a marketing or research application for an FDA-regulated product (drug or device).
<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Data obtained from use of a device on human tissue specimens will be submitted to, or held for inspection by, the FDA in support of a marketing application or research application for an FDA regulated product.

If you answered "NO" to all the questions in Item 1, continue to [Item 2](#).

If you answered "YES" to any of the questions in Item 3, **STOP** – the activity is "human subjects research" and must be submitted to the IRB using a different application.

2. Federal Awards:

Will the 59th MDW receive a direct federal award (e.g., NIH or DHHS grant) to conduct human subjects research, even where all activities involving human subjects are carried out by a non-59 MDW entity (e.g., subcontractor or collaborator)?

☐ Yes. If yes, **STOP** – the activity is "human subjects research" and must be submitted to the IRB using a different application.

☒ No. Continue to [Item 3](#)

3. Research Determination Flowchart:

Q1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?	
<input checked="" type="checkbox"/> No	→ The activity is not research, go to Item 4
<input type="checkbox"/> Yes	→ Q2. The activity is research. Does the research involve obtaining information about living individuals?
<input type="checkbox"/> No	→ The research is not research involving human subjects
<input type="checkbox"/> Yes	→ Q3. Does the research involve intervention or interaction with the individuals?
<input type="checkbox"/> No	→ Q4. Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)?
<input type="checkbox"/> No	→ The research is not research involving human subjects
<input type="checkbox"/> Yes	→ Q5. Is the information private?
<input type="checkbox"/> No	→ The research is not research involving human subjects
<input type="checkbox"/> Yes	→ STOP The activity is "human subjects research" and must be submitted to the IRB using a different application
<input type="checkbox"/> Yes	→ STOP The activity is "human subjects research" and must be submitted to the IRB using a different application

4. Type of Non-Research Activity: How can your non-research activity best be characterized? (*Select one*)

☐ Health Surveillance Study.

This refers to activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under *force health protection programs* of the Department of Defense, including *health surveillance* pursuant to 10 U.S.C. 1074f (medical tracking system for members deployed overseas) and the use of medical products consistent with DoD Instruction 6200.02. Health surveillance is an ongoing part of the medical care and public health care functions closely integrated with timely dissemination of these data to those responsible for preventing and controlling disease or injury (may include emergent or urgently identified or suspected imminent health threats to the population to document the existence and magnitude). Health Surveillance entails monitoring diseases, medical costs, public health clinical parameters, trending analyses, etc. This is NOT considered research.

☒ Medical Quality Assurance/Quality Improvement Study.

[NOTE: If your QA/QI study is considered a systematic research investigation, based on 45 CFR 46.102 (d), and is designed to develop or contribute to generalizable knowledge, it MUST be reviewed by an IRB where:

- You anticipate in advance of conducting the project that you will analyze, interpret, & disseminate the findings of your investigation beyond the scope of your department or division, (i.e., PUBLISH) or
- The knowledge you will gain from your project will be applied beyond quality assurance, service, or training to lead to a new procedure or process.]

QUALITY ASSURANCE: This refers to activities particular to an institution's QA program, such as those activities protected from disclosure by the 59 MDW Quality-Assurance Program, the Department of Veterans Affairs as part of its confidential medical quality-assurance program or other equivalent programs (see applicable policy or instruction). This also refers to activities such as those covered by 10 U.S.C. 1102 and DoD Directive 6025.13, Medical Quality Assurance in the Military Health System, May 4, 2004. The purpose of a Quality Assurance (QA) study is to assure known quality based on a given standard. A QA study should present NO RISK to participants. Such projects are usually for internal auditing purposes only.

QUALITY IMPROVEMENT: Systematic, data-guided activities designed to bring about immediate, positive changes in the delivery of health care in particular settings. QI involves deliberate actions to improve care, guided by data reflecting the effects of local care (e.g., types of practical problem solving; an evidence-based management style; the application of science of how to bring about system change; review of aggregate data at the patient/provider/unit/organizational level to identify a clinical or management change that can be expected to improve care). Improve implies change. QI is generally not considered research – however, QI activities can be research if they are also intended to contribute to generalizable knowledge.

☐ Program Evaluation Study.

This refers to assessments of the success of established programs in achieving mission objectives and program performance when the assessments are for the use of DoD program managers, for example, a survey to determine if program beneficiaries are aware of the availability of program services or benefits. Program evaluations are generally sponsored through the local Commander or higher HQs. Release of study results outside the chain of command requires the local Commander's approval or authorization from higher HQs. It is allowable to publish how a program evaluation was conducted, but the information gathered is NOT for generalizable knowledge. **NOTE: Non-research evaluation is generally designed to assess or improve the program or service rather than to generate knowledge about a disease or condition. Not generally considered a research activity as long as the evaluation is designed to assess or improve the program or service rather than to generate knowledge about a disease or condition.** If the evaluation will be an assessment carried out for publication in general literature regarding non-DoD programs of a similar type, the activity is considered research, do not select this category.

☐ Customer Satisfaction Survey(s) or Interviews.

This refers to surveys of program users to obtain feedback for use by program managers. This is similar to program evaluation. The purpose of these surveys is to improve a specific service or program or develop new services or programs under the control of the individual/organization obtaining the information and not to conduct research. Surveys in general may fall under DoDI 3216.02_AFI 40-402 requirements for additional review by the Air Force Survey Office and coordination regarding the possibility that a Survey Control Number (SCN) may be required should occur early and often until this issue is resolved between the PI and the Protocol Office. Any changes to research involving a survey with an SCN (whether or not exempt from research regulations for the protection of human subjects) should also coordinate with the Protocol Office early in the process of developing the amendment submission to ensure timely determination as to whether further Air Force Survey Office review may be required for the change.

☐ Operational Test and Evaluation (OT&E).

This refers to activities defined in 10 U.S.C. 139(a)(2)(A) and [DoD Directive 5141.2](#), Director of Operational Test and Evaluation (DOT&E), May 25, 2000, as: The field test, under realistic conditions, of any item (or key component) of weapons, equipment, or munitions for the purpose of determining the operational effectiveness and operational suitability of the weapons, equipment, or munitions for operational use, including combat, by typical military users, and the evaluation of the results of such test.

[NOTE: if the purpose of the test is to obtain data on the effects of non-routine interaction with an individual, the activity is considered research, do not select this category.]

☐ Patient Treatment.

Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment.

☐ Class Projects.

Academic projects or student assignments involving collection of data from human subjects when the data is used solely for the purpose of teaching course content (e.g., to teach proficiency in performing certain tasks or using specific tools or methods) and not intended to be used to develop or contribute to generalizable knowledge using the information collected as part of the class project.

☐ Case Reports. *FILL OUT Case Report Form.*

Use of medical information collected from a clinical activity rather than a research activity and presented on no more than three (3) patients. Case reports are generally done by retrospective review of the medical record and highlights a unique treatment, case or outcome. The examination of the case is usually not systematic and there is usually no data analysis or testing of a hypothesis. Investigators must ensure that the HIPAA privacy rules are followed with respect to using or accessing PHI (a HIPAA authorization or waiver may be required).

☐ Biography or Oral History of a Single Individual.

Research involving a single individual is not generalizable knowledge.

☐ Publicly Available Data.

Research involving publicly available information (e.g., census data, labor statistics) does not constitute human research.

☐ Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information.

FORM A
SIGNATURE SHEET

Study Title: Exploring Best Practices in Advance Care Planning

Principal Investigator's Agreement

I understand my institution's policies concerning research involving human subjects and the IRB's policies for protection of human subjects. I am responsible and accountable for the research study and I will:

- protect the rights, safety and welfare of subjects involved in this research (DoDI 3216.02, AFI 40-402)
- ensure research is conducted in an ethical manner and in accordance with all laws, regulations, or policies applicable to the protection for human research subjects and requirements and determinations of the IRB
- personally conduct or oversee those who conduct this research and ensure the study plan is followed, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of subjects and confidentiality of identifiable data, in order to minimize risks to subjects
- supervise study personnel to whom tasks are delegated. Ensure that study personnel: 1) are qualified by training and experience and licensure to perform study-related tasks that have been delegated to them; 2) have an adequate understanding of the research; and 3) follow the IRB-approved protocol, including the recruitment and consent procedures described in the protocol
- ensure that study subjects are provided with: 1) appropriate medical care for any adverse events, including clinically significant CLIA approved laboratory values, related to the research; 2) a qualified contact to answer questions or provide care during the conduct of the research
- obtain, document, and maintain records of informed consent from each subject or when approved by the IRB, the subject's legally authorized representative using the consent document(s) approved by the IRB
- conduct the research in accordance with the protocol approved by the IRB
- initiate changes in the research, including the approved consent form(s), only after IRB approval, except where necessary to eliminate apparent immediate hazards to subjects
- report promptly to the IRB and to the subjects, any significant findings or new information that becomes known in the course of the research that might change the risk of or justification for the research or may otherwise affect the willingness of subjects to participate or to continue to participate in the research
- report promptly to the IRB, any unanticipated problems involving risks to subjects or others in research
- operate within the parameters that have been defined in the HIPAA Authorization regarding Protected Health Information (PHI)
- comply with all applicable FDA regulations, including the Good Clinical Practices Guidelines, and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 50, 56, 312, 600 & 812
- control drugs, biological products, and devices used for research purposes
- submit a progress report for continuing review prior to expiration of IRB approval in accordance with WHASC Policy
- halt all research activities should IRB approval lapse, until the IRB re-approves the research or until special permission is obtained from the IRB to continue previously enrolled subjects if determined to be in their best interests to do so
- promptly submit a final report when the research has been completed or is being closed out prior to completion. It is recommended to notify engaged institutions, clinics, supporting organizations, etc.
- maintain adequate and accurate research records in accordance with institutional and, when applicable, the sponsor or FDA requirements and document ICD Code v70.7 in each research-only visit in AHLTA.

Electronic Signature

PI Signature

(If FDA, electronic signature must contain Name, Date, Time, and Reason)

TRAN.OANH.N.1289
779570

Digitally signed by TRAN.OANH.N.1289779570
DN: c=US, o=U.S. Government, ou=DoD, ou=PKI,
ou=USAF, cn=TRAN.OANH.N.1289779570
Date: 2016.04.26 09:58:13 -05'00'

Electronic Signature - Flight Commander - Resident/Fellow Program Director (Mentor)

Signature: **Hasmin Nales, Maj, USAF, NC**
Internal Medicine, Flight Commander

59 MDOS/SGOM



Squadron Commander's /Division Chief's Certification:

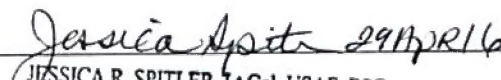
This is to certify that I have reviewed this research protocol and that I attest: to the soundness of the design and its ability to answer the research questions; to the competency of the investigator(s) to conduct the project; and to the presence of sufficient resources required for the research and for protecting research participants' safety.

- I understand that I am responsible for the ethical and legal performance of the research within my unit.
- I certify that the PI understands the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this study.
- I agree to meet with the PI on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be personally available to the PI, as needed.
- If the PI leaves the WHASC without notifying and clearing the Protocol Office, I will ensure the uninterrupted care of research subjects e.g., transfer of PI responsibilities (permanently or temporarily) if necessary via completion of any required forms [i.e. Amendment to change PI or Final Report]
- In my absence or to document delegation of the responsibility, I will arrange for and notify the Protocol Office of a Flight Commander or Resident/Fellow Program Director (Mentor) to assume the above stated Squadron Commander's/Division Chief's responsibilities.

I confirm that the principal investigator is either: <i>(choose one)</i>									
<input checked="" type="checkbox"/>	An <u>employee</u> or <u>agent</u> of this institution/affiliate (e.g., active <u>IAIR</u> with scope that includes this study), OR								
<input type="checkbox"/>	Is not an employee/agent of this institution - I endorse extending the institutional assurance to this investigator subject to approval by the Authorized Institutional Official (<i>see IIA</i>)								
Check the Commander's or Chief's Institution									
<input checked="" type="checkbox"/>	WHASC	<input type="checkbox"/>	SAMMC	<input type="checkbox"/>	UTHSCSA	<input type="checkbox"/>	ISR	<input type="checkbox"/>	Other affiliate: _____

Original Signature – Squadron Commander /Division Chief

Commander Signature:


JESSICA R. SPITLER, Lt Col, USAF, BSC
Commander, 59 MDOS

2017 APR 16 10:00 AM
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